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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,139	01/28/2004	Stefan Schreck	ECV-5541DIVCON	1979

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EDWARDS LIFESCIENCES CORPORATION
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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/766,139

Applicant(s)

SCHRECK, STEFAN

Examiner

Cheryl Miller

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,19,21,22,24-26,38,39 and 43-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18,19,21,22,24-26,38,39 and 43 is/are allowed.
- 6) ☒ Claim(s) 44-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed March 13, 2007 have been fully considered but they are not persuasive for the reasons below.

The applicant has argued that Cribier (US 6,908,481) does not disclose a valve that requires axial movement to connect the two components. The examiner disagrees. Axial movement, before, during or after expansion may occur, and when doing do, will lock the “hooks” into adjacent apertures in the other frame. The applicant has further argued that Cribier does not disclose mutual coupling members. The examiner disagrees. Hooks on one frame and apertures in the stent frame of the other frame are considered mutual coupling members (col.20, lines 33-38).

The applicant has argued that Garrison (US 6,425,916) does not disclose a valve that requires axial movement to connect the two components. The examiner disagrees. Axial movement, before, during or after expansion may occur, and when doing do, will lock the “barbs” or “protrusions” into adjacent apertures in the other frame. The applicant has also argued that in the final product, Garrison’s leaflets are not displaced from the tube of the base. The examiner disagrees. Garrison discloses providing coupling members (barbs, protrusions) on the sub-assembly and on the base (apertures). Because the aperture extends along the entire length of the base, the coupling members of the sub-assembly may couple to any one of the apertures to mechanically connect the two components. The positioning of the coupling members on the two components allows the capability of the two components to mechanically couple to the claimed orientation.

Art Unit: 3738

A new rejection has been made upon further consideration and updated search of the claims, and thus the current rejection is Non-Final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 recites the limitation "the outflow rim" in lines 3 and 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 50-53, 55, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Cribier (US 6,908,481 B2, cited previously). Referring to claim 50, Cribier discloses a two part prosthetic heart valve (see figs.14-15 and respective portions of the specification) comprising a tissue-engagable base (10) that is expandable, and a leaflet subassembly (10') including a

Art Unit: 3738

support structure (stent frame 11 of 10') and three valve leaflets (see valve 14 with three leaflets shown in detail in fig.4b, located between struts 17) attached to the support at commissures (along line 20, seen in detail in fig.7; or at 19 in fig.6b), and further a plurality of discrete connectors (barbs and openings) on the leaflet subassembly (hooks) and the tissue-engagable base (openings in stent frame 10 for hooks to engage; col.20, lines 33-38) that are jointed upon axial movement (see figs.15a-h; when moved axially, hooks will lock into adjacent stent apertures).

Referring to claims 51-53, 55, and 56, Cribier discloses the base to be plastically expandable (col.9, lines 14-22; see fig.15a, 15b). Cribier discloses the support (stent frame 10') comprising a wireform (wire struts 11; seen in figs.14, 15) having alternating cusps and commissures (the zigzag sinusoidal wire mesh having peaks and troughs, which are considered by the examiner to be the "cusps" and "commissures"). Cribier discloses the wireform peaks and troughs to have connectors (hooks; col.20, lines 33-38). The connectors are joined by axial compression, see fig.15c-15f, wherein the subassembly is moving axially and radially to connect (snap in, upon expansion and axial movement) to the base.

Claims 44-48, 50-53 and 55-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Garrison et al. (US 6,425,916, cited previously). Referring to claim 44, Garrison discloses a two part prosthetic heart valve (see figs.8-10) comprising an expandable tissue-engaging base (8), a leaflet subassembly (6, 6C) comprising a support (26) and three heart valve leaflets (38; see fig.11, 34, 38) attached at commissures (commissures considered to be a joining place or line; or near 32 in figs.8-10), and a plurality of discrete mating connectors (protrusions 34 and

Art Unit: 3738

openings 14 seen in figs.9; col.5, lines 29-35, OR barbs 100 and openings 14, see fig.29, 30; col.9, lines 64-67; col.10, lines 1, 16-24) on the leaflet subassembly (openings 14) and the tissue-engaging base (100 OR 34) mechanically coupled together. Applicant has claimed the positioning of the leaflets with respect to the base after they are mechanically coupled.

Garrison's two parts are capable of being located in such relative positioning. That is, Garrison's connector on the subassembly (100 or 34) is adapted to connect into any opening 14 on the base (8), thus capable of the leaflets being positioned outside the tubular body. Garrison has even shown the capability of being able to place the two parts at different positions relative one another, see figs.20, 27, 28, see col.10, lines 26-36. It is inherent that Garrisons subassembly connectors (100 or 34) are capable of being placed in the top outflow end openings 14, such that the leaflets are not located within the tubular body.

Further with respect to claim 44, Garrison's embodiment shown in figures 32-38 may also apply wherein the base is considered (111) and the valve is considered (6D). Clearly the valve leaflets are separate components from the base (111), attached somehow by sutures or adhesive or such. The valve (6D) is shown displaced from the base (111).

Referring to claims 45-48, Garrison discloses a plastically-expandable base (8), see figs.3-4, col.2, lines 1-5, and an elastic wireform (26) subassembly (6) having cusps and commissures (see fig.10, 30). Garrison discloses the subassembly to mechanically couple to the base at a plurality of locations (all along the circumference, where each barb 100 or protrusion 34 is located is a different location; see figs.9, 30). Garrison discloses the base (8) to have mechanical coupling members (openings 14) and the subassembly (6) to have couple members (100 or 34).

Art Unit: 3738

Referring to claim 50, Garrison discloses a two part heart valve comprising an expandable base (8), a leaflet subassembly (6) including a support (stent 26) and three leaflets (38) attached at commissures (see fig.10), and a plurality of discrete mating connectors on each the base and subassembly (the base 8 has opening 14 in which protrusions 100 or 34 of the subassembly 6 engage; col.9, lines 64-67; col.10, lines 1, 16-24).

Referring to claims 51-53 and 55-57, Garrison discloses a plastically expandable base (8; col.2, lines 1-5; figs.3, 4), a subassembly comprising a wireform having cusps and commissures (peaks and valleys of stent 26; see fig.10), mating connectors (100) on the subassembly (6) located on the cusps and commissures (see figs.29, 30) and are joined to the base by axial compression, snap fit (will snap into openings 14 upon expansion after axially positioning). Garrison discloses one of the mating connectors (openings 14) to comprise a partial circle opening (seen in figs.8, 9, portions of openings 14 form a partial circle).

Claims 44, 45, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Jayaraman (US 6,245,102 B1). Jayaraman discloses a two part prosthetic heart valve (fig.10,15) comprising an expandable tissue-engaging base (stent 15), a leaflet subassembly have three leaflets (34, 36, 38), wherein the base and leaflet subassembly are separate components and adapted to mechanically couple to one another (by stitches 47; see col.4, lines 40-47), wherein the leaflets (34, 36, 38) are spaced from the base (see fig.10). Jayaraman discloses connectors (sutures 47, openings in valve leaflets and bend in stent frame).

Art Unit: 3738

Claims 44, 45, 48, 49, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Vince (US 5,163,953, cited in IDS). Vince discloses a two part prosthetic heart valve (fig.3) comprising an expandable tissue-engagable base (stent coil 12), a leaflet subassembly have three leaflets (11), wherein the base and leaflet subassembly are separate components and adapted to mechanically couple to one another (by friction fit, leaflet assembly placed over base, see fig.3), wherein the leaflets (11) are spaced from the base (12; see fig.3). Vince discloses the base (12) to be plastically expandable (col.3, lines 36-50). Vince discloses mechanical connecting member on the base (connecting members being posts 14) and on the sub-assembly (outer overhang of leaflets, which conforms to the posts 14; see fig.3).

Allowable Subject Matter

Claims 18, 19, 21, 22, 24, 25, 26, 3839, and 43 are allowed.

Claim 54 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller



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